AUG 1 6 2002

K021960

Summary of Safety and Effectiveness

Submitted by: Janet Connolly, RAC
Senior Regulatory Affairs Specialist
Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, MA 01730-6230

Device Name: Precision/Optium Point of Care Blood Glucose Test Strips with True Measure Technology

Common Name: Reagent Blood Glucose Test Strip

Classification: Glucose Test System
Class II per 21 CFR 862.1345

Predicate Device: Accu-Chek Comfort Curve Test Strip K980731

Description: The Precision/Optium Point of Care Blood Glucose Test Strips with True Measure Technology is to be used for blood glucose testing with the Precision Xtra/Optium and Precision PCx Blood Glucose Meters. These systems utilize amperometric biosensor technology to generate a current. The size of the current is proportional to the amount of glucose present in the sample, providing a quantitative measure of glucose in fresh whole blood and control solutions.

Intended Use: The Precision/Optium Point of Care Blood Glucose Test Strip with True Measure Technology is intended for in vitro diagnostic use. The test strip quantitatively measures glucose (D-glucose) in fresh venous, arterial, neonatal, and fingertip capillary whole blood. The test strip is indicated for use by health care professionals in health care settings.

This strip may be used with the Precision Xtra/Optium Blood Glucose Meters.

Comparison to Predicate Device: The Precision/Optium Point of Care Blood Glucose Test Strip has similar technological characteristics as the predicate device, Accu-Chek Comfort Curve Test Strip K980731.

Performance Studies:

The performances of the Precision/Optium Point of Care Blood Glucose Test Strip with True Measure Technology was studied in the laboratory and in clinical settings by healthcare professionals. The studies demonstrated that healthcare professionals could obtain blood glucose results that are substantially equivalent to a comparative method.

Conclusion:

Results of laboratory and clinical testing demonstrate that the performance of the Precision/Optium Point of Care Blood Glucose Test Strips when used according to the intended use stated above is acceptable and comparable to the performance to a comparative method.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 1 6 2002

Ms. Janet Connolly, RAC
Sr. Regulatory Affairs Specialist
Abbott Laboratories, MediSense Products
4A Crosby Drive
Bedford, MA 01730-1402

Re: k021960
Trade/Device Name: Abbott Laboratories, MediSense Products Precision Point of Care Blood Glucose Test Strips with True Measure Technology
Abbott Laboratories, MediSense Products Optium Point of Care Blood Glucose Test Strips with True Measure Technology
Regulation Number: 21 CFR 862.1345
Regulation Name: Glucose test system
Regulatory Class: Class II
Product Code: LFR
Dated: June 13, 2002
Received: June 14, 2002

Dear Ms. Connolly:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory-Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATIONS FOR USE FORM

510(k) Number (if known):

Device Name: Abbott Laboratories, MediSense Products Precision Point of Care Blood Glucose Test Strips with True Measure Technology.

Abbott Laboratories, MediSense Products Optium Point of Care Blood Glucose Test Strips with True Measure Technology

Indications For Use:

The Precision/Optium Point of Care Blood Glucose Test Strip with True Measure Technology is intended for in vitro diagnostic use. The test strip quantitatively measures glucose (D-glucose) in fresh neonatal, venous, arterial and fingertip capillary whole blood. The test strip is indicated for use by health care professionals in health care facilities. The test strip is to be used for monitoring diabetes mellitus.

This strip may be used with the Precision Xtra and Optium meters.

for Joan Cooper

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K021960

(PLEASE DO NOT WRITE BELOW THIS LINE--CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-The-Counter Use _____
(Per 21 CFR 801.108)